UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	
v.	)	MDL No: 1:13-md-2419-RWZ
This Document Relates to:	)	
Musselwhite , et al. v. Unifirst Corporation, et al. No: 1:13-cv-13228 –RWZ	)	
Kennedy, et al. v. Unifirst Corporation, et al. No: 1:13-cv-13227-RWZ	)	

DEFENDANTS, ADVANCED PAIN & ANESTHESIA CONSULTANTS, P.C. D/B/A APAC CENTERS FOR PAIN MANAGEMENT AND RANDOLPH Y. CHANG, M.D.'S CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS

I. Introduction[1]

This Court lacks personal jurisdiction over defendants APAC and Dr. Chang with the Complaints otherwise failing to state a claim upon which relief can be granted under applicable Illinois Law. The purchase of the medication--preservative free methylprednisone acetate—MPA—from New England Compounding Pharmacy, Inc ("NECC") by APAC for use in the medical care of the Illinois based and residing plaintiffs in Illinois is insufficient to satisfy the due process requirements for personal jurisdiction under the due process clause. Under no possible construction of the complaint, can it be said that either APAC or Dr. Chang purposefully availed themselves of being sued in Massachusetts.

[1] Defendants, Advanced Pain & Anesthesia Consultants, P.C. d/b/a APAC Centers for Pain Management ("APAC") and Randolph Y. Chang, M.D., submit this Consolidated Memorandum of Law in Support of their Motion to Dismiss as to Musselwhite v. Advanced Pain & Anesthesia Consultants, P.C., et al. No. 1:13-cv-13228-RWZ and Kennedy v. Advanced Pain & Anesthesia Consultants, P.C., et al. No. 1:13-cv-13227-RWZ.

As to the asserted claims, it is undisputed that neither APAC nor Dr. Chang played any role in the manufacture or sterility practices of NECC and had no knowledge of any contamination of the medication prior to receipt and administration to plaintiffs as part of the medical care being provided. There is no recognized duty of "due diligence" upon either APAC or Dr. Chang as to the purchase of medications from a compounding facility with any failure to obtain individual prescriptions in the purchase of the medication having no causal role in the contamination of the medication by NECC. Further, neither APAC nor Dr. Chang can be liable under the Illinois Consumer Protection Act or Illinois Product Liability law as they are not sellers or distributors of medications but medical care providers who provided the medication as part of the their on-going medical care and services on behalf of the plaintiff patients. There is likewise no actionable gross negligence or punitive damage claim under Illinois law nor any factual basis to find any 'agency" relationship between APAC or Dr. Chang and NECC.

II Statement of the Case and Relevant Facts

These two actions were initiated directly in this Court on or about December 20, 2013 by the respective filing of a "Short Form Complaint." Both plaintiffs are Illinois residents who allege they were administered MPA by Dr. Chang in 2012 with the MPA, manufactured and/or compounded by NECC, turning out to have had been contaminated by fungus due to the sterility practices of NECC resulting in alleged injury. Kennedy Complaint; Musselwhite Complaint Both plaintiffs allege the following causes of action: (1) Negligence and Gross Negligence (Count III); (2) Violation of the Illinois Consumer Protection Statute – Ill. Comp. Stat. Ann. Ch. 815, 505/1 et seq. (Count IV); (3) Battery (Count VII); (4) Failure to Warn (Count VIII); (5) Illinois Product Liability Law (Count IX); 6) Agency (Count X); 7) Civil Conspiracy (Count XI); and 8) Punitive Damages (Count XIV). *See* Short Form Complaints.

III Standard

"In multidistrict litigation . . . a court must apply the law of the forum where the case was *filed* to determine personal jurisdiction." *In re Pabst Licensing GMBH & Co. KG Litig.*, 590 F. Supp. 2d 94, 98 (D.D.C. 2008)(emphasis added). In a suit directly filed to a MDL transferee court, the proper analysis is whether the transferee court has personal jurisdiction over the defendant. *In re Heartland Payment Systems, Inc. Customer Data Security Breach Litig.*, 2011 WL 1232352, *4 (S.D. Tex. 2011)(unreported)(finding no personal jurisdiction against directly-filed defendant following MDL transfer). While directly filed cases may provide some efficiency benefits, they also may, as is the case here, present jurisdictional issues. *Id.* (citing *In re Vioxx Prods. Liab. Litig.*, 478 F. Supp. 2d 897, 904 n.2 (E.D. La. 2007).[2] Accordingly, the plaintiffs must prove that Massachusetts has jurisdiction over the Illinois medical defendants.

As to the applicable standard of review as to personal jurisdiction issues, plaintiff bears the burden of demonstrating that jurisdiction over the defendant is proper. *Sawtelle v. Farrell*, 70 F.3d 1381, 1387 (1st Cir. 1995). Plaintiff must (where there is no evidentiary hearing) make a *prima facie* showing of personal jurisdiction by offering "evidence that, if credited, is enough to support findings of all facts essential to personal jurisdiction." *Boit v. Gar-Tec Products, Inc.*, 967 F.2d. 671, 675 (1st Cir. (1992), see also *Foster-Miller, Inc. v. Babcock & Wilcox Canada*, 46 F. 3d 138, 145 (1st Cir. 1995). Further, where as here, plaintiff alleges multiple causes of action, personal jurisdiction over the defendant must be proper for each and every cause of action. See *Debrecent v. Bru-Tell Hearing Corp*, 710 F. Supp. 15, 19 (D. Mass. 1989) ("Where one

[2] *See also In re Norplant Contraceptive Prods. Liab. Litig*., 946 F.Supp. 3,4 (E.D. Tex. 1996)(discouraging plaintiffs from direct-filing); *see also In re: Train Derailment Near Amite, Louisiana, On October 12, 2002*, 2004 WL 224573 (E.D. La. 2004)(context of complex litigation does not alter analysis, rather "[t]he personal jurisdiction determination depends solely on the defendant's conduct in and contacts with the forum state").

complaint contains two claims…there must be an independent basis for the assertion of personal jurisdiction for each claim. Jurisdiction over one claim does not imply jurisdiction over any other.").[3]

As to Rule 12(b)(6) and in diversity actions, federal courts apply federal procedural rules and a state's substantive law. *Rodriguez v. Glock, Inc.*, 28 F. Supp. 2d 1064, 1067, (N.D. Ill. 1998); *Bourke v. Dun & Bradstreet Corp.*, 159 F.3d 1032 (7th Cir. 1998). To survive a motion to dismiss, plaintiff must allege facts that "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009)(quoting *Twombly,* 550 U.S. at 556). The Court need not accept the plaintiff's legal conclusions as true or other "labels and conclusions" as "formulaic recitation of a cause of action's elements will not do." *Twombly*, 550 U.S. at 555. "A plaintiff 'cannot satisfy federal pleading requirements merely by attaching bare legal conclusions to narrated facts which fail to outline the bases of their claims.'" *Zurich Capital Mkts., Inc. v. Coglianese*, 332 F. Supp. 2d 1087, 1100, (N.D. Ill. 2004). Dismissal is appropriate if plaintiff's well-pleaded facts do not "possess enough heft to show that plaintiff is entitled to relief." *Ruiz Rivera v. Pfizer Pharms., LLC,* 521 F.3d 76, 84 (1st Cir. 2008) (quotations and original alterations omitted).

IV. Law and Argument

A. This Court Lacks Personal Jurisdiction Over APAC and Dr. Chang

i. Jurisdictional Prerequisites

[3] Since both cases were filed directly into this Court, this Court is to apply the Massachusetts Long-Arm Statute and jurisdictional jurisprudence of the First Circuit. See, e.g., *In re: Chinese Manufactured Drywall Products Liability Litigation*, 767 F. Supp. 2d 649, 656 and n.2 (E.D. La. 2011) (applying form count's jurisdictional law in MDL case).

In a MDL proceeding such as here, the transferee court can only exercise personal jurisdiction if it existed in the transferor court.[4] See e.g., *In re Chinese*, 742 F.3d at 583 n. 8; *In re Papst Licensing GMBH & Co., Litigation*, 590 F. Supp. 2d 94 (D.D. C. 2008). When subject matter jurisdiction is premised on diversity, a federal court may assert personal jurisdiction over a non-resident defendant only if the plaintiff establishes both that: (a) the forum state's long-arm statute authorizes the exercise of "jurisdiction over the defendant, and (b) the defendant has sufficient "minimum contacts" with the forum state such that the court's jurisdiction does not offend constitutional due process. *Sawtelle*, 70 F. 3d at 1387; *Kowalski v. Doherty, Wallace, Pillsbury & Murphy* 787 F. 2d 7, 8 (1st Cir. 1986); *Negron-Torres v. Verizon Communications Inc*., 478 F. 3d 19, 24 (1st Cir. 2007). The Supreme Judicial Court of Massachusetts has interpreted the state's long-arm statute as co-extensive with the outer limits of the Constitution thus leaving the pertinent inquiry, here, under the Constitution; *Sawtelle*, 70 F.3d at 1388.

The constitutional inquiry is focused on whether the particular defendant's contacts with Massachusetts were such that requiring that defendant to defend a lawsuit there does not offend traditional notions of fair play and substantive justice. *Bond Leather Co., Inc. v. Q.T. Shoe Mfg., Co., Inc.*, 764 F. 2d 928, 933 (1st Cir. 1985); *International Shoe Co. v. Washington*, 326 U.S. 310, 316, 66 S. Ct. 154, 158 (1945). Central is whether the defendant has "purposefully availed itself of the privilege of conducting activities within the form state, thus invoking the benefits and protections of its laws." *Bond Leather*, 764 F. 2d at 933 quoting *Hanson v. Denckla*, 357 U.S. 235, 253 (1958). Indeed, minimum contracts analysis focuses on the expectation of the defendant requiring that his conduct bear such a "substantial connection with the forum [s]tate"

[4] Pursuant to statute, cases in the MDL will be remanded to their home districts for trial when the multi-district proceeding concludes.

that the defendant "should reasonably anticipate being haled into court there." *Burger King Corp. v. Ruckewicz*, 471 U.S. 462, 473-75 (1985).

To determine whether plaintiff has alleged sufficient facts to supports a finding of specific personal jurisdiction,[5] the First Circuit "divides the constitutional analysis into three categories; 1) relatedness, 2) purposeful availment; and 3) reasonableness." *Negron-Torres,* 478 F. 3d. at 24-25. "An affirmative finding on each of the three elements of the test is required to support a finding of specific jurisdiction." *Phillips Exeter Academy v. Howard Phillips Fence*, 196 F. 3d 284, 288 (1st Circ. 1999).

ii. Neither APAC nor Dr. Chang Purposely Availed Themselves of Suit in Massachusetts

The sole basis for jurisdiction over APAC and Dr. Chang is APAC's purchase of the medication (MPA) from NECC. It is undisputed that plaintiffs are both residents of Illinois and that all care including the administration of the MPA was done in Illinois. The alleged injury is claimed to have occurred in Illinois as well as all subsequent care with neither APAC nor Dr. Chang having any dealings with NECC beyond APAC's purchase of the MPA.

Under no conceivable analysis can it be said that the action taken – purchase of the MPA – amounts to a purposeful decision by either APAC or Dr. Chang – as Illinois care providers providing medical care to Illinois plaintiffs in Illinois –to participate in the local economy and to avail itself of the benefits and protections of the forum (i.e. Massachusetts). See *Ganis Corp of California v. Jackson*, 822 F. 2d. 194, 198 (1st Cir. 1987); *Anderson v. Century Products Co.*, 943 F. Supp. 137, 143 (D.N.H. 1996); see also *Bond Leather*, 764 F. 2d at 933 (noting the First Circuit's "special concern for formulating a jurisdictional rule that would protect wholly passive

[5] There can be no possible argument that there exists general jurisdiction over APAC or Dr. Chang as they had no continuous and systematic activity in the forum state (i.e. Massachusetts). See *Negron-Torner*, 478 F. 3d at 25-26 and cases cited. Regardless of whether specific or general, constitutional analysis turns on the existence of "minimal contacts." Id.

purchasers, who do no more than place an order with an out of state merchant and await delivery."); *United Elec. Radio & Mach. Wkrs. V. 163 Pleasant St. Corp*., 960 F.2d 1080, 1087 (1st Cir. 1992)(recognizing that the test is "whether the defendant attempted to participate in the commonwealth's economic life"). Indeed, it has been long held that contracting to purchase with a Massachusetts seller is not sufficient to impose personal jurisdiction over a non-resident. See *Bond Shoe*, 764 F. 2d at 933-34; *See also Vetrotex Certainteed Corp. v. Consolidated Fiber Glass Prods. Co.*, 75 F. 3d 147, 152 (3rd Cir. 1996)(passive purchaser did not purposefully avail itself to forum state when it merely responded to plaintiff's solicitation); *Stuart v. Spademan*, 772 F. 2d 1185, 1193 (5th Cir. 1985)(informational communications in furtherance of a contract between a resident and non-resident does not establish the purposeful activity necessary for a valid assertion of personal jurisdiction over the non-resident defendant); *Whittaker Corp. v. United Aircraft Corp.*, 482 1079, 1084-85 (1st Cir. 1973)(finding no personal jurisdiction as to two of three defendants that placed orders and awaited delivery and did not visit forum state until after items were shipped); *Cook v. Jenkins*, 2008 WL 1819128 (D. Mass. 2008)(no personal jurisdiction due to insufficient contacts aside from formation of contract); *A-Connoisseur Transp. Corp. v. Celebrity Coach Inc.*, 742 F. Supp. 39 (D. Mass. 1990)(non-resident defendant merely responded to forum-state company's contractual solicitation, finding insufficient contacts to establish personal jurisdiction); *L&P Converters, Inc. v. H.M.S. Direct Mail Service, Inc.*, 634 F. Supp. 365, 366 (D. Mass. 1986) (applying contract plus analysis and finding no jurisdiction over non-resident's classic passive purchasing of forum-state seller's products).

There remains no alleged facts that either APAC or Dr. Chang each individually and respectfully benefited from the protections of Massachusetts law in anyway. APAC was at best a passive purchaser and "even if a defendant's contacts with the forum are deemed voluntary, the

purposeful availment prong of the jurisdictional test investigates whether the defendant benefitted from those contacts." Making payments to NECC for compounded medication resulted in no conceivable benefit to APAC or Dr. Chang from the protection of Massachusetts law.

ii. The Gestalt Factors Further Establish the Lack of Personal Jurisdiction

The need for reasonableness in the due process analysis requires application of the Gestalt factors which include (a) the defendant's burden of appearing; (b) the forum state's interest in adjudicating the dispute and effective relief; (c) the plaintiff's interest in obtaining convenient and effective relief; (d) the judicial system's interest in obtaining the most effective resolution of the controversy; and (e) the common interests of all sovereigns in promoting substantive social policies. *Adelson v. Hananel*, 652 F.3d 75, 83 (1st Cir. 2011). The weaker the plaintiff's showing as to the purposeful availment and relatedness prongs, the less a defendant need show in terms of unreasonableness to defeat jurisdiction. *Ticketmaster-New York, Inc. v. Alioto,* 26 F.3d 201, 203 (1st Cir. 1994).

Although not controlling, there is a measurable burden in forcing Dr. Chang and/or APAC to litigate in Massachusetts.[6] They are, respectively, an Illinois based and/or practicing medical provider and clinic. They do not live or work in Massachusetts with the medical care at issue all taking place in Illinois and to Illinois residing and living plaintiffs. Massachusetts' interest in adjudicating a dispute between Illinois residents and an Illinois medical clinic and licensed and practicing physician is fleeting, if not non-existent. The fact that APAC purchased the medication from Massachusetts-based NECC does not provide a compelling state interest to adjudicate the claims being brought by the Illinois plaintiffs against the Illinois based medical

[6] The Gestalt factors must be applied as to the particular forum where the case was initiated not in the context of the MDL proceeding. This particular action was filed directly in the District of Massachusetts not in Illinois and then transferred to the MDL. There must be proper jurisdiction in the forum where the suit was filed.

clinic and practicing physician. Furthermore, a forum state has a diminished interest in cases where the injury, and the factors that gave rise to the injury, occurred outside the forum state's borders. *Sawtelle v. Farell*, 70 F.3d 1381, 1395 (1st Cir. 1995).

As to the judicial system's interest in obtaining the most effective resolution of the controversy and the common interest of all sovereigns in promoting substantive policies, these factors, again, are to not be evaluated based on the MDL proceeding, but as to the filing by plaintiffs directly in the District of Massachusetts. The most pertinent policy argument—a state's ability to provide a convenient forum for its residents to redress injuries by out-of-forum actors—is lacking here, as both the plaintiffs, defendants, and acts giving rise to the alleged injury all occurred in Illinois. *See Burger King Corp. v.* Rudzewicz, 471 U.S. 462, 473 (1985); *Sawtelle*, 70 F.3d at 1381. There is no constitutionally proper jurisdiction over APAC and/or Dr. Chang in the District of Massachusetts.

B. Plaintiffs' Complaints Fail to Sufficiently Allege a Claim for Negligence or Gross Negligence.

1. Illinois Law Does Not Impose A "Due Diligence" Tort Duty As Alleged by Plaintiffs In Their Complaints.

Under Illinois law, a plaintiff must allege sufficient facts to meet each element of a negligence claim: (1) the existence of a duty; (2) a breach of the duty; and (3) an injury proximately resulting therefrom. *Sullivan v. Edward Hospital*, 209 Ill. 2d 100,112, 806 N.E.2d 645 (II. Sup. 2004); *Purtill v. Hess*, 111 Ill. 2d 229, 241-42, 489 N.E.2d 867 (Ill. 1986); See also *Dundee Cement Co. v. Chemical Lab., Inc.*, 712 F.2d 1166, 1168 (7th Cir. 1983); *Rodriguez v. Glock, Inc.*, 28 F. Supp. 2d 1064, 1070 (N.D. Ill. 1998). There can be no recovery in a tort for negligence unless the defendant has breached a duty owed to the plaintiff. *Adams v. N. Ill. Gas*

Co., 211 Ill. 2d 32, 44, 809 N.E.2d 1248 (Ill. 2004). The existence of a duty is a question of law for the court to decide. *Id.* at 43-44.

A determination of whether a duty exists is multifactorial, and a court looks to certain relevant factors, including: (1) the reasonable forseeability that the defendant's conduct may injure another, (2) the likelihood of an injury occurring, (3) the magnitude of the burden of guarding against such injury, and (4) the consequences of placing that burden on the defendants. *Kirk v. Michael Reese Hospital & Medical Center*, 117 Ill. 2d 507, 526, 513 N.E.2d 387, (Ill. 1987). In regard to foreseeability and the existence of a duty, an injury may not be considered reasonably foreseeable where there are no allegations that the health care professions either knew or had reason to know of the problems associated with a medication. *Id.*

Here, plaintiffs contend that there is a legal duty of "due diligence" upon health clinics and physicians when purchasing medications from a compounding pharmacy. Plaintiffs contend that this "due diligence" duty derives and/or is supported by the American Society of Health-System Pharmacy (ASHP) Guidelines on Outsourcing Sterile Compounding Services. Illinois law, however, does not recognize any such due diligence tort duty. Illinois does not impose a duty on physicians and/or medical clinics to regulate the pharmacies from which they lawfully purchase medications, nor does Illinois law impose a duty on physicians to visit and/or evaluate a licensed pharmacy's compounding facility prior to purchasing medications as Plaintiff has alleged. There is no authority supporting such a "due diligence duty." There is no support for such an imposition and no reported case has ever held or found such a duty. It was the regulatory obligation of the Massachusetts Board of Pharmacy, not either APAC or Dr. Chang to regulate and license NECC and to ensure NECC complied with Massachusetts' pharmacy laws. APAC was well within its legal right to purchase medication from a fully licensed pharmacy

without conducting its own investigation and purported "due diligence" as to NECC's sterility practices including any inspection of its facilities or otherwise ensuring the pharmacy's compliance with applicable law. Additionally, Illinois law does not require physicians and/or clinics to purchase medications from an FDA regulated drug manufacturer as Plaintiffs suggest. Again, no such case stands for such a proposition. Accordingly, there is no such due diligence obligation or duty upon either APAC or Dr. Chang mandating the dismissal of the plaintiffs negligence claim.[7]

Contrary to the allegations, APAC and Dr. Chang were not required to follow the American Society of Health-System Pharmacy (ASHP) Guidelines on Outsourcing Sterile Compounding Services, nor do such guidelines establish any duty under Illinois law. ASHP is simply a professional organization for Health-System Pharmacies. It is not a governing body that has any authority over the actions of Illinois physicians and/or medical clinics. Thus, any "guidelines" promulgated by the organization do not establish and/or constitute a due diligence obligation and a legal tort duty on physicians/clinics purchasing compounded medications. Such guidelines are simply professional guidelines that have no bearing on duties imposed by Illinois law.

Illinois courts have rejected the notion that non-binding aspirational guidelines may constitute the standard of care in negligence actions. *See, e.g.*, *Poelker v. Warrensburg Latham*

[7] Even if the court were to find a new duty under Illinois law, it would not be applied retroactively. Under Illinois law, courts give decisions that change the law prospective application when retroactive application would be inequitable. *Deichmueller Const. Co. v. Industrial Com'n*, 151 Ill. 2d. 413, 415 603 N.E.2d 516 (Ill. 1992). In reaching the prospective application decision, a court considers whether the new decision was foreseeable. Cases of first impression that are not clearly foreshadowed by pending litigation at the time of the underlying action (or inaction) are not foreseeable. *See id.* Here, no such foreshadowing exists. The court next considers whether a retroactive application of the decision is necessary to advance the purpose behind the court's holding. *Id.* Lastly, the court considers whether retrospective application would result in injustice or hardship. *Id.* Here, establishing a new precedent that places an affirmative duty that could not have been contemplated by Dr. Chang or APAC, and to defendants knowledge has never been recognized by a court of law anywhere, surely constitutes hardship.

Comm. Unit School Dist. No. 11, 251 Ill. App. 3d 270, 284, 621 N.E.2d 940 (Ill. App. Ct. 4th Dist. 1993)(rejecting national high school standards, adopted by state elementary school association, regulating track meets as standard of care because regulations did not have force of law); *Bulger v. Chicago Transit Auth.*, 345 Ill. App. 3d 103, 197, 801 N.E.2d 1127 (Ill. App. Ct. 1st Dist. 2003)(transit authority internal rules governing driver safety were guidelines that did not have force of law). Here, the proposition that the ASHP guidelines establish a standard of care over Dr. Chang or APAC is even more removed because these guidelines have not been adopted by any regulatory body that purports to have control over Illinois physicians or pain clinics. Simply put, Illinois law does not impose a duty on physicians to regulate pharmacies and/or engage in any type of due diligence prior to lawfully purchasing medications from a licensed pharmacy such as NECC. Illinois law has never recognized any such duties with respect to physicians and/or clinics.

Moreover, it is for the Illinois General Assembly, not the courts, to determine whether any such duties should be imposed on physicians and/or clinics. See *Nudd v. Matsoukas*, 6 Ill. App. 2d 504, 516 128 N.E.2d 609 (Ill. App. Ct. 1st Dist. 1955) (rev'd on other grounds (1956) ("the plaintiffs urge that this court should change long and firmly established rules of law and declare a new public policy for the State. We believe that such far-reaching questions are primarily for the legislature."): See generally, *Bissen v. Fujii*, 446 A.2d 429, 431 (Haw. 1970) ("we should recognize that although courts at times arriving at decisions have taken into consideration social needs and policy it is the paramount rule of the legislature as a coordinate branch of court government to meet the needs and demands of changing times and legislate accordingly); Stephen Presser, *The Development and Application of Common Law*, 8 Tex. Rev. L. & Pol. 291, 296-97 (2004) ("[role of judge] you recognize that your job is to preserve the past,

with its core system of values. You defer to the other institutions of republican government when it comes to policy making …); *Badillo v. Am. Branch*, 16 P.3d 435, 441 (Nev. 2001) (lack of consensus as to medical monitoring militates toward rejecting judicial expansion of common law); *Coombes v. Florio*, 877 N.E. 567, 583 (Mass. 2007) (Marshall, C.J. dissenting) (advocating rejection of expanding physicians' tort liability given how reasonable minds may differ on issue).

To be sure, APAC and Dr. Chang are obligated to exercise reasonable care in the care and treatment of their patients. Fundamentally, this duty of reasonable care is premised on a consensus in the medical community. Not only is there not a single case supporting the due diligence duty sought to be imposed, but there is no support of any established consensus for such a duty. The imposition of such a due diligence duty would mark a drastic expansion of existing law and one better left to the legislature not the courts. Because there is no actionable due diligence duty of care upon either APAC or Dr. Chang, Count III of Plaintiffs Complaint fails to state a claim upon which relief can be granted.

2. To The Extent Plaintiffs Allege and Rely Upon The Failure to Obtain Individual Prescriptions, Plaintiffs' Complaints Fail To Sufficiently Allege Causation.

As this Court is well aware, causation is an essential element of a negligence claim. *Rodriguez v. Glock, Inc.*, 28 F. Supp. 2d 1064, 1070 (N.D. Ill. 1998); *Wehmeier v. UNR Indus., Inc.*, 213 Ill. App. 3d 6, 29, 572 N.E.2d 320 (Ill. App. Ct. 4th Dist. 1991). Proximate cause encompasses the concepts of cause in fact and legal cause. *See Rodriguez v. Glock, Inc.*, 28 F. Supp. 2d 1064, 1070 (N.D. Ill. 1998). The first step in analyzing any causation issue is determining whether the defendant's conduct was a cause of the plaintiff's injury (cause in fact). Once it is determined that the defendant's conduct was a cause of the injury, the second step involves determining whether the defendant should be legally responsible (legal cause). *Id.*

Illinois courts generally apply two tests when analyzing causation in fact: the "substantial factor" test and the "but for" rule. Under the "substantial factor" test, the defendant's conduct is said to be a cause of an injury "if it was a material element and a substantial factor in bringing it about." *Rodriguez*, 28 F. Supp. 2d at 1070*; see also Tragarz v. Keene Corp.*, 980 F.2d 411, 420 (7th Cir. 1992). Under the "but for" rule, "the defendant's conduct is not a cause of an event if the event would have occurred without it." *Rodriguez*, 28 F. Supp. 2d at 1070.

Next, to be a legal cause of an injury, and thus its proximate cause, the cause must produce the injury through a natural and continuous sequence of events that is unbroken by any effective intervening cause. *See Unger v. Eichleay Corp.*, 244 Ill. App. 3d 445, 451, 614 N.E.2d 1241 (Ill. App. Ct. 3rd Dist. 1993). Accordingly, to establish legal causation, plaintiff must show that the alleged action or conduct at issue was an actual cause of the injuries rather than a mere condition. *Rodriguez v. Glock, Inc.*, 28 F. Supp. 2d 1064, 1070-1072 (N.D. Ill. 1998) (citing *Merlo v. Public Serv. Co. of Northern Illinois*, 381 Ill. 300, 316-17, 45 N.E.2d 665 (Ill. 1942).

Where there are no facts that could establish that an act or omission by the defendant proximately caused an injury to plaintiffs, then the issue is appropriately decided as matter of law. *Roberts v. Sisters of St. Francis Health Services, Inc.*, 198 Ill. App. 3d 891, 897, 556 N.E.2d 662 (Ill. App. Ct. 1st Dist. 1990); *Gill v. Foster*, 232 Ill. App. 3d 768, 777-778, 597 N.E.2d 776 (Ill. App. Ct. 4th Dist. 1994). Proximate cause cannot be speculative and that there must be facts linking a breach of the standard of care or breach of some duty to an injury to plaintiffs. *Mengelson v. Ingalls Health Ventures*, 323 Ill. App. 3d 69, 74, 751 N.E.2d 91 (Ill. App. Ct. 1st Dist. 2001).

It is alleged that that APAC and Dr. Chang were negligent in failing to provide patient-specific prescriptions and/or in providing "fake" patient lists in order to purchase medication

from NECC. Assuming arguendo such allegations are true – which they are not – such allegations are insufficient to plead causation, either factual or proximate. NECC's failure to properly manufacture and apply proper sterility practices as to the preservative-free MPA is the source of the contamination, not APAC or Dr. Chang alleged failure to provide patient-specific prescriptions. As such, the contamination would have occurred irrespective of whether patient-specific prescriptions were provided when purchasing the medication from NECC. Accordingly, the allegation that Dr. Chang and/or APAC failed to provide patient-specific prescriptions is insufficient to establish causation as a matter of law.

3. Illinois Does Not Recognize A Cause of Action for Gross Negligence.

Illinois law does not recognize gross negligence as a cause of action or an independent ground for recovery. See *Mercury Skyline Yacht Charters v. Dave Matthews Band, Inc.*, 2005 U.S. Dist. LEXIS 29663, 31, 2005 WL 3159680 (N.D. Ill. Nov. 22, 2005) (citing *Chicago, R. I. & P. R. Co. v. Hamler*, 215 Ill. 525, 74 N.E. 705 (Ill. 1905).) The court in *Mercury Skyline* noted that courts have interpreted the Illinois Supreme Court's ruling in *Chicago, R.I. & P. Ry. Co.* as eliminating the cause of action for gross negligence in Illinois. Specifically, the Seventh Circuit cited to *Chicago, R.I. & P. Ry. Co.* and held that 'Illinois does not recognize gross negligence as an independent ground for recovery.'" *In Merit Ins. Co. v. Colao*, 603 F.2d 654, 659 (7th Cir. 1979). Thus, plaintiffs' claims for gross negligence must be dismissed as a matter of law.

C. There is No Actionable Claim Under The Illinois Consumer Fraud and Deceptive Business Practices Act.

Plaintiffs' claims relevant to the Illinois Consumer Fraud and Deceptive Business Practices Act [hereinafter referred to as the Illinois Consumer Fraud Act] should be dismissed. *See generally*, 815 ILCS 505/2 (2014). A successful count premised on the Illinois Consumer Fraud Act must allege, with specificity and particularity, facts from which fraud is the necessary

or probable inference, including what misrepresentations were made, when they were made, who made the misrepresentations and to whom they were made. *Connick v. Suzuki Motor Co.*, 174 Ill. 2d 482, 496-497, 675 N.E.2d 584 (Ill. 1996). Specifically, to allege a claim under the Illinois Consumer Fraud Act Plaintiffs must show: (1) a deceptive act or practice by defendant; (2) defendant's intent that Plaintiffs rely on the deception; and (3) that the deception occurred in the course of conduct involving trade and commerce; (4) the Plaintiffs sustained actual damages, and (5) such damages were proximately caused by the defendant's deception. *Walton*, 692 F. Supp. 2d at 1023; See also *Connick*, 174 Ill. 2d at 501.

Importantly, federal court in Illinois was presented with allegations similar to those in the instant case, and the court found that the plaintiff had not sufficiently alleged a cause of action pursuant to the Illinois Consumer Fraud Act. See *Walton v. Bayer Corp. (In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab, Litig.)*, 692 F. Supp. 2d 1012, 1023-1024 (S.D. Ill. 2010). In *Walton*, plaintiff's complaint primarily alleged, just as the complaint in the instant case, that a prescription drug maker failed to prevent, guard against or inform the public about problems associated with the drug. *Id.* at 1023. The *Walton* court noted that if it assumed that the facts relevant to the improper conduct of the drug company were true, then the healthcare professional at issue would have had no knowledge regarding the alleged dangerous propensities of the drug. *Id.* In affirming the dismissal of the Illinois Consumer Fraud Act count, the *Walton* court held that the plaintiff's claim could not succeed against the healthcare provider where plaintiff failed to meet obligation of identifying with particularity the fraudulent conduct and that the healthcare professional intended that plaintiff rely on that conduct. *Id.*

Just as in *Walton*, if the drug manufacturer was making or compounding this medication in a manner that was unsafe or required an additional warning, then these defendants would have

had no knowledge of the dangerous propensities of the drug or the contamination. Moreover, Plaintiffs' entire fraud claim in the instant case is built around after-the-fact billing records. Plaintiffs alleged that some of the bills for the injections referenced a steroid called DepoMedrol, and not the name of the steroid that was actually used. However, these bills were generated after the injections, so the bills cannot be evidence that the healthcare professionals at issue "intended" that Plaintiffs rely on a misrepresentation of defendants before undergoing the injections.

There are no facts that show that these billing errors or "misrepresentations" were intended to induce Plaintiffs to go forward with the injections. Further, there are no assertions that these billing records or errors caused any injury to Plaintiffs. Allegations of statutory fraud pursuant to the Illinois Consumer Fraud Act must be pled with specificity and particularity. *Id.* There is no such specificity and particularity in the Complaints at issue. Thus, Plaintiffs cannot make a claim under the Illinois Consumer Fraud Act. Count IV of the Complaints at issue should, therefore, be dismissed.

D. Plaintiffs Consented To The Steroidal Injections at Issue; Therefore, There Is No Viable Claim for Battery.

Under Illinois law, a person commits battery when he or she unlawfully touches another. *Mink v. University of Chicago*, 460 F. Supp. 713, 717 (N.D. Ill. 1978). "To be liable for battery, the defendant must have done some affirmative act, intended to cause an unpermitted contact." *Id.* In the medical context, a cause of action for battery may be maintained where there is a complete lack of consent by the patient to the treatment. *Moore v. Eli Lilly & Co.*, 626 F. Supp. 365, 368 (D. Mass. 1986) (citing *Lojuk v. Quandt*, 706 F.2d 1456, 1460 (7th Cir. 1983); *Mink v. University of Chicago*, 460 F. Supp. 713, 717 (N.D. Ill. 1978).)

If the patient has consented to the doctor's treatment, then the patient may not later maintain an action in battery. *Carter v. Ameji*, 2011 U.S. Dist. LEXIS 100449, 28, 2011 WL 3924159 (C.D. Ill. Sept. 7, 2011). Battery is an intentional tort in Illinois that is separate and distinct from a claim for a lack of informed consent. (*Id.*) In the case at bar, it is undisputed that Plaintiffs signed consents before undergoing the injections at issue, so the battery counts should be dismissed.

E. Plaintiffs' Complaints Do Not Properly Allege Violations of Illinois Products Liability Law.

1. The Master Complaint Does Not Set Forth A Claim For Violations Of Illinois Products Liability Law.

In their Short Form Complaints, Plaintiffs purport to incorporate by reference from the Master Complaint, a claim against these Clinic Related Defendants for alleged violations of the Illinois Products Liability law (hereinafter "OPLA"). See Short Form Complaints, at p. 4. However, the Master Complaint does not set forth a claim for violations of the Illinois Products Liability law. To the contrary, Count IX of the Master Complaint sets forth a claim against the Tennessee Clinic Related Defendants only for alleged violations of Tennessee Products Liability law. See Master Complaint at p. 76. Unlike several other counts in the Master Complaint where Plaintiffs set forth statutory claims against the Clinic Related Defendants by listing the various state statutes that formed the basis if such claims – for example, Count IV and Count XII – Count IX is limited to the Tennessee Clinic Related Defendants and sets forth allegations specific to Tennessee law.

Further, in their Short Form Complaints, Plaintiffs have not set forth any allegations specific to their Illinois Products Liability claim. Without the necessary allegations in either the

Master Complaint or the Short Form Complaints, Plaintiffs have not sufficiently pleaded a claim for violations of the Illinois Products Liability in this case.

2. As Providers of Professional Services These Clinic Related Defendants Cannot Be Subjected To Strict Liability Pursuant to Illinois Products Liability Case Law.

Illinois products law does not apply to the medical services that were provided to Plaintiffs by these Clinic Related Defendants. In Illinois, if the defendants are providing a medical service, as opposed to selling a product, then a claim for strict product liability cannot be asserted. *Greenberg v. Michael Reese Hospital*, 83 Ill. 2d 282, 291, 415 N.E.2d 390 (Ill. 1980). A claim for strict product liability is comprised of three elements: (1) the product was defective, in it was unreasonably dangerous in light of its intended use; (2) the product was defective when it left the manufacturer's control; and (3) the defective condition of the product proximately caused Plaintiffs' injuries. *Samansky v. Rush-Presbyterian-St. Luke's Medical Center*, 208 Ill. App. 3d 377, 567 N.E.2d 386 (Ill. App. Ct. 1st Dist. 1990).

In the case at bar, the product lability claims and strict liability claims should be dismissed because the Clinic Related Defendants were providing medical services, not selling a product, when they performed the epidural injection procedures on Plaintiffs. In *Greenberg v. Michael Reese Hospital*, 83 Ill. 2d 282, 291, 415 N.E.2d 390 (Ill. 1980), the Illinois Supreme Court refused to apply strict liability to a hospital for the administration of radiation therapy. The Court held that the hospital was providing a service when administering procedures involving radiation to patients. *Id.* The same is true for the instant case. Products lability law does not apply to the epidural injection procedures that were preformed on Plaintiffs. The healthcare professionals were providing medical services when they preformed these procedures. *Id.*

Further, the Seventh Circuit did not apply products liability case law to the medical procedures that were preformed by the healthcare professionals in *Stiffler v. Lutheran Hosp.*, 965 F.2d 137, 141 (7th Cir. 1992). The Seventh Circuit noted that it was significant that "[t]he Hospital never placed Stiffler's prosthesis in the stream of commerce; it never promoted it for purchase by the public; and it was in no better position than Stiffler to examine the product and discover the defect." *Id.* Similarly, these Clinic Related Defendants did not place this drug into the stream of commerce, they never promoted it for purchase, and they were in no better position than the general public to discover the contamination.

F. Plaintiffs' Complaints Do Not Sufficiently Set Forth a Failure to Warn Claim under Illinois Law.

A duty to warn arises "where the product possesses dangerous propensities and there is unequal knowledge with respect to the risk of harm, and the manufacturer, possessed of such knowledge, knows or should know that harm may occur absent a warning." *Miller v. Rinker Boat Co*., 352 Ill. App. 3d 648, 672, 815 N.E.2d 1219 (Ill. App. Ct. 4th Dist. 2004) (citing *Sollami v. Eaton*, 201 Ill. 2d 1, 19, 772 N.E.2d 215 (Ill. 2002).) If there is no unequal knowledge with respect to the risk of harm, then this duty to warn is not applicable. The duty to warn is determined by an objective analysis, *i.e.*, the awareness of an ordinary person. *Klen v. Asahi Pool, Inc.*, 268 Ill. App. 3d 1031, 1035, 643 N.E.2d 1360 (Ill. App. Ct. 1st Dist. 1994). The determination of whether a duty to warn exists is a question of law. *Sollami v. Eaton*, 201 Ill. 2d 1, 7, 772 N.E.2d 215 (Ill. 2002).

The Complaints at issue do not contain any allegations that the use of preservative-free MPA or a compounded drug, generally, presents a high-risk to patients or is unreasonably dangerous. Additionally, the Complaints do not contain any allegations that the Clinic Related

Defendants knew or should have known that using preservative-free MPA or a compounded drug is unsafe or more dangerous than using a drug produced by an FDA-regulated manufacturer. There are no allegations of an unequal knowledge with respect to the risk of harm, and the manufacturer, possessed of such knowledge, knows or should know that harm may occur absent a warning. Further, the Complaint does not allege Plaintiffs would have in fact refused to undergo the epidural steroidal injections at issue if she had been informed the drug being used was preservative-free MPA that had been obtained from a compounding pharmacy. Quite simply, the Complaint does not contain the necessary allegations to establish a common law failure to warn claim.

Moreover, contrary to Plaintiffs' claims, Illinois law does not impose a duty on physicians to inform patients where drugs are produced or that a drug being used in the course and scope of their treatment was produced at a compounding pharmacy instead of an FDA-regulated pharmaceutical manufacturer. Thus, any failure on the part of the Clinic Related Defendants to provide such information cannot form the basis of a common law failure to warn claim. Accordingly, Plaintiffs' claims of a failure to warn are insufficient as a matter of law and must be dismissed.

G. Plaintiffs' Complaints Do Not Adequately Allege the Elements Necessary to Create an Agency Relationship under Illinois law.

Plaintiffs asserting a theory of agency must plead specific facts establishing a principal-agent relationship and Plaintiffs cannot simply plead the legal conclusion that such a relationship exists. *Connick v. Suzuki Motor Co.*, 174 Ill. 2d 482, 497, 675 N.E.2d 584 (Ill. 1996). An agency relationship is a fiduciary relationship in which the principal has the right to control the agent's conduct and the agent has the power to act on the principal's behalf. *Zahl v. Krupa*, 365 Ill. App. 3d 653, 661, 850 N.E.2d 304 (Ill. App. Ct. 1st Dist. 2006). "Conversely, an independent

contractor undertakes to produce a certain result, but is not controlled in regard to how that result is achieved." *Cutler v. Quality Terminal Servs., LLC*, 2012 U.S. Dist. LEXIS 26023, 34, 2012 WL 669052 (N.D. Ill. Feb. 29, 2012)(citing *Lang v. Silva*, 306 Ill. App. 3d 960, 972, 715 N.E.2d 708 (Ill. App. Ct. 1st Dist. 1999).

The facts alleged by Plaintiffs do not and cannot establish an agency relationship. At best, the facts in Plaintiffs' Complaints establish the existence of an independent contractor relationship. Thus, the agency claims in Count X should be dismissed. If this court were to accept Plaintiffs' agency theory, then any time of consumer agrees to purchase a product that purchaser becomes the principal of the company that sold her the product.

Plaintiffs allege, without a scintilla of factual support, that these Clinic Related Defendants were the principal of NECC. Yet, nothing in the Complaints asserts how the Clinic Related Defendants in Illinois could control the compounding of this medication by NECC in Massachusetts. Instead, the Complaints allege that the Clinic Related Defendants had contract that controlled the "procurement" or receipt of the drugs at issue. Thus, Plaintiffs' have only alleged that these Clinic Related Defendants entered into contract "to produce a certain result." *Cutler*, 2012 U.S. Dist. LEXIS 26023; See also *Lang*, 306 Ill. App. 3d at 972. The result contracted for, according to the Complaints, was the delivery or "procurement" of the drug at issue. No facts have been alleged that the Clinic Related Defendants controlled "how that result [was] achieved." *Id.*

Thus, the facts in Plaintiffs' complaints when viewed in a light most favorable to Plaintiffs only establish, at best, the existence of an independent contractor relationship between the Clinic Defendants and NECC for the "procurement of MPA." The agency claims against these defendants should, therefore, be dismissed because the party alleging the existence of an

agency relationship bears the burden of proving that such a relationship exists. *Wallace v. Alexian Brothers Medical Center*, 389 Ill. App. 3d 1081, 1086, 907 N.E.2d 490 (Ill. App. Ct. 1st Dist. 2009).

H. The Allegations in Plaintiffs' Complaints Do Not Meet the Requirements of a Civil Conspiracy Claim Under Illinois Law.

Illinois defines a civil conspiracy "a combination of two or more persons for the purpose of accomplishing by concerted action either an unlawful purpose or a lawful purpose by unlawful means." *McClure v. Owens Corning Fiberglas Corp.*, 188 Ill. 2d 102, 133-134, 720 N.E.2d 242 (Ill. 1999). To prove a civil conspiracy Plaintiffs must alleged that an injury was caused by an unlawful overt act performed by one of the parties to the agreement, and the overt act that caused the injury was done pursuant to and in furtherance of the common scheme. *Borsellino v. Goldman Sachs Group, Inc.*, 477 F.3d 502, 509 (7th Cir. 2007). Further, the Seventh Circuit held that the pleading requirements of Rule 9(b) are to be applied to the Plaintiffs' claim for civil conspiracy where the conspiracy claim was premised on alleged fraud. *Id. See also Gros v. Midland Credit Mgmt.*, 525 F. Supp. 2d 1019, 1028, 2007 U.S. Dist. LEXIS 66621, 18 (N.D. Ill. 2007). Lastly, "[a]ccidental, inadvertent, or negligent participation in a common scheme does not amount to a civil conspiracy." *Foodcomm Int'l v. Barry*, 463 F. Supp. 2d 818, 830-831, 2006 U.S. Dist. LEXIS 82910, 26-27 (N.D. Ill. 2006).

In the case bar, Plaintiffs alleges that these Clinic Related Defendants provided "bogus patient lists" in order to purchase MPA in bulk. (See Master Compl., at Paragraphs 338-342.) However, Plaintiffs' Complaints do not tie this alleged overt act to knowingly entering into an agreement that could result in the contamination of the MPA. These patient lists are not alleged to have caused the contamination. The sterility of NECC's compounding practice has not been alleged to be linked to these alleged "bogus patient lists." Thus, Plaintiffs have not pled a cause

of action for civil conspiracy. Even if this court were to assume as true that "bogus patient lists" were created, these lists or the agreement related to these lists was not entered into by these Clinic Related Defendants knowing that it could have or would have led to the contamination of MPA or the injury at issue. The alleged agreement at issue in this case had nothing to do with the production of the drug nor were there any allegations that the agreement relevant to these patient lists caused a non-sterile environment. Thus, the civil conspiracy claims in Counts XI should be dismissed.

I. The Allegations Against APAC and Dr. Chang Are Insufficient to Support a Punitive Damages Claim Under Illinois Law.

In Count XIV of the Complaints, Plaintiffs have attempted to assert a punitive damages claim against these Clinic Related Defendants. See Master Complaint at p. 86; Short Form Complaint at 4. However, none of the allegations are sufficient to support a punitive damages claim. Indeed, a punitive damages claim is a derivative claim that cannot stand when the underlying tort claims are insufficient as a matter of law. Accordingly, Count XIV of the Complaints fails to state a claim upon which relief can be granted.

In Illinois, punitive damages will be awarded "only where the defendant's conduct is willful or outrageous due to evil motive or a reckless indifference to the rights of others." *Trull v. Taylor* (In re Estate of Feinberg), 2014 IL App. 112219, P61, 2014 Ill. App. LEXIS 43, 47, 2014 WL 455547 (Ill. App. Ct. 1st Dist. 2014) (citing *Franz v. Calaco Dev. Corp.*, 352 Ill. App. 3d 1129, 1137, 818 N.E.2d 357 (Ill. App. Ct. 2d Dist. 2004). Because punitive damages are not favored in the law, they are available only in cases where the wrongful act complained of is characterized by "wantonness, malice, oppression, willfulness, or other circumstances of aggravation." *Franz*, 352 Ill. App. 3d. at 1137 (citing *E.J. McKernan Co. v. Gregory*, 252 Ill. App. 3d 514, 536, 623 N.E.2d 981) (Ill. App. Ct. 2nd Dist. 1993).

Misconduct for which punitive damages are imposed must be outrageous, and it must be committed with an evil motive or a reckless indifference to the rights of others. *Tri-G, Inc. v. Burke, Bosselman & Weaver*, 222 Ill. 2d 218, 264, 856 N.E.2d 389, (Ill. 2006); See also *Loitz v. Remington Arms Co.*, 138 Ill. 2d 404, 414-16, 563 N.E.2d 397 (Ill. 1990) (collecting authorities). Illinois Courts have held that the deterrent function of punitive damages is similar to that of a criminal penalty. "Because of their penal nature, punitive damages are not favored in the law, and the courts must take caution to see that punitive damages are not improperly or unwisely awarded." *Kelsay v. Motorola, Inc.*, 74 Ill. 2d 172, 188, 384 N.E.2d 353 (Ill. 1978).

CONCLUSION

Based on the foregoing, defendants Advance Pain & Anesthesia Consultants, P.C. d/b/a APAC Centers for Pain Management and Randolph Y. Chang M.D. respectfully request that their Motion to Dismiss be ALLOWED.

Respectfully Submitted
The Defendants
Advanced Pain & Anesthesia Consultants, PC
d/b/a APAC Centers for Pain Management and
Randolph Y. Chang, M.D.
By their attorney

/s/ Tory A. Weigand

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I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on **May 7, 2014**

/s/ Tory A. Weigand